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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,713	07/22/2002	Carl V. Manion	11146/11005	7559

7590 10/14/2003  
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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/088713

Applicant(s)

Manion

Examiner

PAK, J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-16 is/are pending in the application.
- 4a) Of the above, claim(s) 6-11 is/are withdrawn from consideration
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-5 and 12-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other: \_\_\_\_\_

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Claims 3-16 are pending in this application.

Restriction to one of the following inventions is required under 35 USC 121, 37 CFR 1.475, and PCT Rule 13:

Group I, claims 3-5 and 12-16, drawn to method for treating high whole blood viscosity *in a patient* with aspartame and other alkyl esters of aspartylphenylalanine.

Group II, claims 6-7, drawn to method for reducing whole blood viscosity *in a blood sample* with aspartame and other alkyl esters of aspartylphenylalanine.

Group III, claims 8-11, drawn to method for monitoring the reduction of whole blood viscosity in a patient, comprising various collecting, measuring and comparing steps involving blood samples and viscosity measurements.

The three groups lack a unity of invention. The three groups are directed to three separate and distinct method inventions, and the inventions are not so linked as to form a single general inventive concept. There is no special technical feature among the inventions that define a contribution over the prior art that each invention makes. In vivo and in vitro effects are distinct, and can encompass divergent utilities, such as providing suitable blood samples for a different subject. The monitoring invention requires steps involve an algorithm that is not necessarily encompassed in the treatment per se invention. These

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features define a contribution, which each of the claimed invention, considered as a whole, make over the prior art, which are not shared by all of the invention groups.

Therefore, the inventions lack a unity of invention for the reasons stated above.

During a telephone conversation with Ms. Eugenia Hansen on 9/29/2003, a provisional election was made without prejudice and with traverse to prosecute the invention of Group I. Affirmation of this election must be made by applicant in replying to this Office Action. Claims 6-11 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being directed to non-elected inventions, and claims 3-5 and 12-16 will presently be examined.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5 and 12-16 are rejected under 35 USC 102(b) as being anticipated by Edmunson et al. (US 5,654,334).

Edmunson et al. explicitly disclose aspartame and C2-6 esters of aspartylphenylalanine (claim 1). Edmunson's method is for decreasing pain in a

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patient (claim 1). Patients with osteoarthritis are explicitly disclosed (Examples 1-2 on columns 4-15). Effective amount is about 80-320 mg (claim 1; column 4, lines 10-15). It is noted that for an adult, of say 75 kg, this is equivalent to about 1-4 mg/kg.

It is recognized that Edmunson et al. do not explicitly disclose treating for high whole blood viscosity or abnormally viscous whole blood in a patient. However, applicant admits in the specification that arthritic patients are associated with increased whole blood viscosity (p. 1, lines 19-21). Therefore, prior treating of patients with osteoarthritis would have had the necessary effect of also treating for high or abnormal viscous whole blood viscosity. The claims are thereby anticipated.

For these reasons, all claims must be refused.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1200